UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,869	12/09/2003	Carl D. Wahlstrand	1023-318US01	6690

28863 7590 07/28/2005

SHUMAKER & SIEFFERT, P. A.
8425 SEASONS PARKWAY
SUITE 105
ST. PAUL, MN 55125

EXAMINER	
GREENE, DANA D	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/731,869	WAHLSTRAND ET AL.	
	Examiner	Art Unit	
	Dana D. Greene	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12/9/03* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/29/04, 6/20/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 11-23, 32-42, and 51-55 stand rejected under 35 U.S.C. §102(b) as being anticipated by Meltzer (US 5,645,586, hereinafter "Meltzer"). Meltzer is considered to disclose:

a first module that includes control electronics within a first housing (*see* col. 3, ln. 20-35, fig. 2, Meltzer). The disclosed segment 23 is considered to anticipate the claimed first module because both contain electronics that control the functioning of the implantable medical device;

a second module that includes a second housing (*see* col. 3, ln. 20-35, fig. 2, and col. 4, ln. 49-60, Meltzer). The disclosed segment 24 is considered to anticipate the claimed second module because both include a power source within the housing to provide power to the control electronics in the form of a battery or capacitor;

an overmold that at least partially encapsulates the first and second housings (*see* col. 4, ln. 44-48, Meltzer). The disclosed biocompatible polymer is considered to anticipate the claimed overmold because both materials can be silicone and are flexible enough to allow for easy manipulation during implantation such that they allow the implantable device to conform to the cranium or other body part.

With reference to claims 2, 16, 17, 23, 32-34, Meltzer is considered to teach:

a first module that includes control electronics housed within a first housing (*see* col. 3, ln. 20-35, fig. 2, Meltzer). The disclosed segment 23 is considered to anticipate the claimed first module because both contain electronics that control the functioning of the implantable medical device;

a second module that includes a power source that provides power to the first module housed within a second housing (*see* col. 3, ln. 20-35, fig. 2, and col. 4, ln. 49-60, Meltzer). The disclosed segment 24 is considered to anticipate the claimed second module because both include a power source within the housing to provide power to the control electronics in the form of a battery or capacitor;

an interconnect member that flexibly couples the first and second modules (*see* col. 3, ln. 30-35, Meltzer). The disclosed complementary contact is considered to anticipate the claimed interconnect member because both couple the first and second modules and allow multiple degrees of freedom of movement between modules of the implantable medical device.

With regards to claim 11, Meltzer is considered to disclose:

the implantable medical device, wherein the overmold completely encapsulates the first and second modules (*see* col. 4, ln. 44-49, Meltzer). The disclosed polymer is considered to anticipate the claimed overmold because both are capable of completely surrounding the entire housing with the biocompatible polymer.

Referring to claims 12-15, Meltzer is considered to teach:

the implantable medical device, wherein the overmold does not encapsulate a portion of each of the first and second modules, and each of the portions is proximate to a cranium of a patient when the implantable medical device is implanted on the cranium (*see* col. 2, ln. 60-67, col. 3, ln. 50-55, and col. 4, ln. 44-49, Meltzer). The disclosed material surrounding the housing is considered to anticipate the claimed overmold because both can at least partially encapsulate the first and second housings for easy contact with the cranium.

Referring to claims 18 and 35, Meltzer is considered to disclose:

substantially cylindrical first and second housings (see col. 4, ln. 1-15, Meltzer). The disclosed cylindrical shape of the segment is considered to anticipate that of the claimed housing because both make implantation of the IMD within the periphery of the patient easier.

Regarding claims 19, 36, and 52, Meltzer is considered to disclose:

a lead connection module formed within the overmold to receive one of a lead that includes an electrode and a lead extension that is coupled to the lead (see col. 3, ln. 5-15, Meltzer). The disclosed lead connection housing is considered to anticipate the claimed lead connection module because both are formed within the overmold or the biocompatible polymer coating to receive a lead or lead extension;

a conductor that extends from the lead connection module to the first module, wherein the first housing comprises a hermetic feedthrough to receive the conductor and the conductor electrically couples the electrode to the first module (*see* col. 4, ln. 16-35, Meltzer). The disclosed interconnect member is considered to anticipate the

claimed member because both connect the modules and include conductors arranged for sliding contact such that pivotal movement is possible and that interconnection is easily obtained.

With reference to claims 21, 22, 38, 53, and 54, Meltzer is considered to disclose:

the flexible implantable medical device such that a shape of the implantable medical device is capable of being manipulated (*see* col. 2, ln. 60-67 and col. 4, ln. 64-67, Meltzer). The disclosed flexibility is considered to anticipate that of the claimed device because both enable the device to conform or follow the shape, outline, or contour of the implantation site such as the cranium or chest area with ease.

Referring to claims 39-41, Meltzer is considered to disclose:

a first module that includes control electronics housed within a first housing a first module that includes control electronics housed within a first housing (*see* col. 3, ln. 20-35, fig. 2, Meltzer). The disclosed segment 23 is considered to anticipate the claimed first module because both contain electronics that control the functioning of the implantable medical device;

a second module that includes a power source that provides power to the first module housed within a second housing (*see* col. 3, ln. 20-35, fig. 2, and col. 4, ln. 49-60, Meltzer). The disclosed segment 24 is considered to anticipate the claimed second module because both include a power source within the housing to provide power to the control electronics in the form of a battery or capacitor;

a hermetic interconnect member that flexibly couples the first and second modules, wherein the interconnect member is flexible in a plurality of directions and allows the first and second modules to have a plurality of degrees of freedom of movement relative to each other (*see* col. 3, ln. 19-53, Meltzer). The disclosed ribbon cable is considered to anticipate the claimed interconnect member because both couple the first and second modules and allow multiple degrees of freedom of movement between modules of the implantable medical device.

With reference to claims 20, 37, 42 and 51, Meltzer is considered to disclose:

a first module comprising control electronics and a therapy delivery circuit housed within a first housing, wherein the control electronics control delivery of stimulation by the therapy delivery circuit (*see* col. 1, ln. 10-37 and col. 3, ln. 19-35, Meltzer). The disclosed segment is considered to anticipate the claimed first module because both configurations are adapted to conform to the implant site within the patient ant to receive components of the IMD capable of delivering stimulus or therapy to the patient. In this connection, Meltzer teaches an electronic assembly contained within the first housing;

a second module comprising a power source within a second housing that provides power to the control electronics and the therapy delivery circuit (*see* col. 3, ln. 20-35, fig. 2, and col. 4, ln. 49-60, Meltzer). The disclosed segment 24 is considered to anticipate the claimed second module because both include a power source within the housing to provide power to the control electronics in the form of a battery or capacitor;

an interconnect member that flexibly couples the first and second modules and includes a conductor for delivery power from the power source to the control electronics and the therapy delivery circuit (*see* col. 4, ln. 16-35, Meltzer). The disclosed interconnect member is considered to anticipate the claimed member because both connect the modules and include conductors arranged for sliding contact such that pivotal movement is possible;

a flexible overmold that at least partially encapsulates the first and second housings (*see* col. 4, ln. 44-48, Meltzer). The disclosed biocompatible polymer is considered to anticipate the claimed overmold because both materials can be silicone and are flexible enough to allow for easy manipulation during implantation such that they allow the implantable device to conform to the cranium or other body part.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3-10, 24-31, 43-50, 56 and 57 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Meltzer in view of Reischl et al. (US 6,176,879, B1, hereinafter "Reischl"). Meltzer is considered to disclose the claimed invention as discussed above except for the claimed rechargeable power source. However, Reischle is considered to disclose the claimed rechargeable power source (*see* col. 2, ln. 40-48, Reischl). It would have been obvious to one of ordinary skill in the art to combine the teachings of

Meltzer with the rechargeable power supply unit of Reischl for the purpose of providing power to the individual components to ultimately deliver therapeutic agents to the patient. In this connection, it would have been obvious to one of ordinary skill in the art to combine the teachings of Meltzer with the receiving coil of Reischl for the purpose of inductively receiving energy from an external recharging unit through the skin of the patient to recharge the power source.

Claim 55 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Meltzer in view of Thompson et al. (US 6,567,703 B1, hereinafter "Thompson"). Meltzer is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed pulse generator. However, Thompson is considered to teach the pulse generator (*see* col. 6, ln. 8-27, Thompson). It would have been obvious to one of ordinary skill in the art to combine the teachings of Meltzer with the pulse generator of Thompson for the purpose of delivering electrical stimulation to the patient.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Claims 1- 57 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/731,638. The two modules of the claimed application possess an identical housing to that of the copending application. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to provide an implantable medical device for implantation in the head of a patient with variations of a first and second module including a flexible overmold to cover the modules.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana D. Greene whose telephone number is (571) 272-7138. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dana D. Greene

Dana D. Greene

George Manuel